

SEP 16 2001

Covance 7209-105

VALIDATION RESULTS FOR METHOD ACNE					
ANALYTE	MATRIX	MEAN	RELATIVE STD. DEV. (%)	RANGE	SEE (conc)
ANALYTE	Acetonitrile				
MATRIX	Exhalate				
DATE	7-Sep				
LLOQ	(Provide Statistical Criterion)	6.07 µg/mL	5.83	5.43 - 6.41	0.145
STANDARD ERROR OF ESTIMATE OF QC SAMPLES (concentration units) ($SEE = S.D./\sqrt{(\# \text{ of determinations})}$)					
Representative		High QC 60.0µg/mL Med QC 30.0µg/mL Low QC 0.15.0µg/mL	5.72 8.40 4.82	50.0 - 58.7 21.8 - 30.0 13.0 - 15.2	
DESCRIPTIVE INFORMATION ON INSTRUMENT RESPONSE					
Function (Linear, Quadratic, etc.) (Representative)	Linear (1/X weighting)				
Slope	2549				
Intercept	1556				
Other (R)	0.99943				
RECOVERY (as a %)					
High QC in (matrix)= 60.0µg/mL	90.1	5.72	83.3 - 97.8	1.38	
Med QC in (matrix)= 30.0µg/mL	89.2	8.41	72.7 - 100	2.00	
Low QC in (matrix)= 15.0µg/mL	93.8	4.81	86.7 - 101	1.21	
Results with different sample amounts (results of QC evaluations) intra-assay					
Representative	LLOQ QC= 7.50µg/mL Low QC= 15.0µg/mL Med QC= 30.0µg/mL High QC= 60.0µg/mL	6.07 14.1 27.0 53.5	5.83 5.04 8.19 5.08	5.43 - 6.41 13.1 - 15.1 23.6 - 30.1 84.3 - 94.3	0.145 0.290 0.902 1.11
Results with different sample amounts (results of QC evaluations) inter-assay					
Representative	LLOQ QC= 7.50µg/mL Low QC= 15.0µg/mL Med QC= 30.0µg/mL High QC= 60.0µg/mL	6.07 14.1 26.8 54.0	5.83 4.82 8.40 5.72	5.43 - 6.41 13.0 - 15.2 21.8 - 30.0 50.0 - 58.7	0.145 0.182 0.601 0.826
STABILITY (assuming any degradation is linear):					
a) Room Temperature in Matrix (+/- %/24 hrs)	60.0µg/mL	93.0			
b) Freeze/thaw (+/- % /3 cycles)	60.0µg/mL	103			
c) Injector (+/- %/24 hrs)	60.0µg/mL	97.2			

Exhalate Summary
10:08 PM9/20/01Analyst: _____
Reviewed By: _____

PM3006635894